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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/815,297	03/31/2004	Timothy James Jegla	018512-005920US	8561
20350 7590 06/11/2007 TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834			EXAMINER CHERNYSHEV, OLGA N	
			ART UNIT 1649	PAPER NUMBER
			MAIL DATE 06/11/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/815,297	Applicant(s) JEGLA, TIMOTHY JAMES	
	Examiner Olga N. Chernyshev	Art Unit 1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-14 and 16-18 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-14 and 16-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>4/30/7</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 30, 2004 has been entered.
2. Claims 12-14 and 16-18 are pending and under examination in the instant office action.
3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.
4. Applicant's arguments filed on April 30, 2007 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 101

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 12-14 and 16-18 stand rejected under 35 U.S.C. 101 because the claimed invention is drawn to an invention with no apparent or disclosed specific and substantial credible utility for reasons of record in section 5 of Paper mailed on March 02, 2006 and in section 6 of Paper mailed on August 23, 2006.

Applicant traverses the rejection by stating that it is improper to “place[s] the initial burden to establish utility on Applicant” and refers to specific sections of MPEP to support this statement (p. 4 of the Response). This argument has been given careful consideration but it is unpersuasive that the Examiner did not established “lack of utility by evidence and reasoning”, *Id.*, because the evidence and reasoning as why the instant claimed invention lacks specific and substantial credible utility and, as such, is not enabled, are presented in official documents of record mailed on March 02, 2006 and August 23, 2006.

Applicant further refers to a declaration filed by Dr. Douglas Krafte and alleges that the declaration “provides explanation as to why the identification of Kv10.1 has a specific and substantial utility and why a person of skill in the art would find this utility credible, particularly in the context of drug discovery” (p. 4 of the Response).

The Declaration of Krafte under 37 CFR 1.132 filed on April 30, 2007 is insufficient to overcome the rejection of claims 12-14 and 16-18 based upon 35 U.C.S 101/112, first paragraph, as set forth in the last Office action for reasons set forth below.

The Declaration presents the following statements:

“The potassium channels are indicated in signal transduction during various biological processes such as neuronal integration, cardiac pacemaking, muscle contraction, hormone secretion, cell volume regulation, lymphocyte differentiation, and cell proliferation. Given this knowledge and the specific expression of Kv10.1 in the CNS, male reproductive organs, and retina, one of ordinary skill in the art would recognize the Kv10.1 channel as a therapeutic target for treating CNS or vision disorders or for regulating male infertility” (section 6 at p. 2 of the Declaration);

Since the sequence of Kv10.1 is identified, “one of ordinary skill in the art can thus conduct routine testing to identify activators or inhibitors of a Kv10.1 potassium channel useful for modulating signal transduction in the cells where this potassium channel is present (*e.g.*, the brain, spinal cord, prostate, testis, and retina), and therefore useful for treating neurological disorders and vision problems, or for modulating male infertility” (section 7 at p. 3);

“[I]t is perfectly reasonable to expect that the targeting of a Kv10.1 channel, a voltage-gated channel expressed at a high level in the CNS, ocular tissue, and male reproductive system, is an appropriate strategy for treating disorders in the CNS or vision, or conditions related to male infertility, whether or not such abnormality is directly caused by altered Kv10.1 activity” (section 8 at pp. 3-4).

Thus, the Declaration is in agreement with the knowledge in the art and the position fully explained by the Examiner in the previous office actions of record that the potassium channel family represents a broad class of molecules involved in variety of basic physiological processes (“neuronal integration, cardiac pacemaking, muscle contraction, hormone secretion, cell volume regulation, lymphocyte differentiation, and cell proliferation”, see above). As such, the utility of this instant novel and currently claimed Kv10.1 channel cannot be immediately recognized as specific and substantial credible by virtue of belonging to a class of molecules with a specific and well-established utility because potassium channels do not have common physiological function. Further, there appears to be no reasonable explanation given in the Declaration or presented in the instant specification, as filed, as why one skilled in the art would recognize this instant Kv10.1 channel as being specifically associated with diseases of CNS or vision disorders or with male infertility based solely on the pattern on the tissue distribution of Kv10.1.

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Moreover, one readily appreciates that “CNS disorders and vision disorders and male infertility” represent extremely large number of unrelated disorders of different etiology and course of pathology. Without knowing a biological role or physiological significance of this instant Kv10.1 channel in at least one of those disorders, a skilled practitioner would have to resort to a significant amount of further research and experimentation, not limited to “routine testing to identify activators or inhibitors of a Kv10.1 potassium channel” (section 7 of the Declaration”. Clearly, disclosure of “tissue distribution for the Kv10.1 ion channel” (section 9 of the Declaration), does not provide for immediate use of the Kv10.1 in treating CNS disorders or any other disorders, as no evidence of record has been brought forward to indicate any specific association of Kv10.1 channel with any disorder or disease.

At pp. 6-7 of the Response, Applicant submits that “the Examiner has apparently confused the claimed subject matter of this application with something Applicant does not claim” and states that it is the polypeptide of SEQ ID NO: 3, the Kv10.1 channel itself, and not its modulator that is currently claimed. Applicant’s attention is directed to section 9 of Krafte Declaration, which states “the modulators [of an ion channel of interest] can then be used for treating diseases and conditions relevant to the ion channel”. Thus, the utility of the instant claimed Kv10.1 polypeptide is based upon assertion that it is useful in treatment of “neurological disorders and vision problems, or for modulating male infertility”, which is asserted to be achieved by administration of modulators of the Kv10.1 channel. Since the instant specification, or Applicant’s Response, or the Declaration of Krafte, fail to identify any specific pathological condition, which is specifically associated with this instant claimed Kv10.1 potassium channel, there appears to be no scientifically supported reasoning to support a

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conclusion that administration of an activator or inhibitor (“modulator”) of the Kv10.1 channel would have any effect on any of the following: “neuronal integration, cardiac pacemaking, muscle contraction, hormone secretion, cell volume regulation, lymphocyte differentiation, and cell proliferation” (section 6 of the Declaration).

At pp. 7-8 of the Response, Applicant compares the instant claimed invention with Example 8 of the Utility Guidelines and argues that the situation in Example 8 can be directly compared to the present application. Applicant’s arguments have been carefully considered but are not persuasive for the reasons that follow.

In Example 8, a compound A, that inhibits an enzyme XYZ, to treat diseases caused or exacerbated by enzyme XYZ, has been found to have a utility because enzymes have a well established utility in the art. However, this appears to be not the factual situation here. Each enzyme has a substrate specificity, which defines its unique biological function; therefore, an inhibitor of a specific enzyme obviously would have a specific and substantial credible utility. In the instant case, Kv10.1 potassium channel is defined as belonging to a group of channels with broad range of diverse physiological functions (see section 6 of the Declaration, for example, the instant specification and reasons of record earlier in the instant office action). Modulating of potassium current does not stand for a specific condition but rather corresponds to one of the most universal biological characteristics of a live cell, thus, presenting an invitation to use a polypeptide of the instant invention as an object of further research, which, as it has been determined by the courts, alone does not support patentability. The proper analysis of the instant claims, which are drawn to an isolated polypeptide of yet undetermined significance, should be made in light of Example 12 of those guidelines, which explains why an isolated nucleic acid

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encoding an “orphan receptor” lacks utility in the absence of the disclosure of a specific role for either the nucleic acid or protein in a known disease or disorder or a physiological process which one would wish to manipulate for clinical effect.

Finally, Applicant is advised that reliance to two post-filing publications, Exhibit B and D (pp. 4-5 of the Response), cannot support the utility of the instant invention, as 35 U.S.C. 101 makes it clear that the invention must be fully disclosed at the time of filing, which precludes any further experimentation to establish the utility of the claimed polypeptide. Further, publication of Singh et al., 1998 (p. 5), describes mutations in a different unrelated potassium channel, KCNQ2, and as such, the relevance of that publication to the instant claimed invention is not clear.

The U.S. Court of Appeals for the Federal Circuit recently addressed the utility requirement in the context of a claim to DNA. *See In re Fisher*, 2005 WL 2139421 (Sept. 7, 2005). The *Fisher* court interpreted *Brenner v. Manson*, 383 U.S. 519, 148 USPQ 689 (1966), as rejecting a “de minimis view of utility” 2005 WL 2139421, at *4. The *Fisher* court held that § 101 requires a utility that is both substantial and specific. *Id.* At *5. The court held that disclosing a substantial utility means “show[ing] that an invention is useful to the public as disclosed in its current form, not that it may be useful at some future date after further research. Simply put, to satisfy the ‘substantial’ utility requirement, an asserted use must show that the claimed invention has a significant and presently available benefit to the public.” *Id.*

The court held that a specific utility is “a use which is not so vague as to be meaningless.” *Id.* In other words, “in addition to providing a ‘substantial’ utility, an asserted use must show that the claimed invention can be used to provide a well-defined and particular benefit to the public.” *Id.*

The *Fisher* court held that none of the uses asserted by the applicant in that case was either substantial or specific. The uses were not substantial because “all of Fisher’s asserted uses represent merely hypothetical possibilities, objectives which the claimed ESTs, or any EST for that matter, could possibly achieve, but none for which they have been used in the real world.” *Id.* at *7.

Just as in *Fisher* case where the Board reasoned that use of the claimed ESTs for the identification of polymorphisms is not a specific and substantial utility because “[w]ithout knowing any further information in regard to the gene represented by an EST, as here, detection of the presence or absence of a polymorphism provides the barest information in regard to genetic heritage,” (*Id.*, slip op. at 15), in the instant case, the disclosure of the structure and tissue distribution of the novel potassium channel provides no meaningful information with regards to the specific readily available benefit to the public. As such, the instant claimed invention does not meet the requirements of 35 U.S.C. 101 and, therefore, the instant rejection is maintained.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 12-14 and 16-18 also stand rejected under 35 U.S.C. 112, first paragraph.

Specifically, since the claimed invention is not supported by either a clear asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Conclusion

9. No claim is allowed.
10. This is a continued examination of applicant's Application No. 10/815,297. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Olga N. Chernyshev, Ph.D.
Primary Examiner
Art Unit 1649

May 30, 2007